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Attorneys for Plaintiffs Anne McCabe, Frances Martinez and the Proposed Plaintiff Class

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW YORK

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	:	<b>COMPLAINT</b>
	:	
	:	<u>CLASS ACTION</u>
	:	
IN RE: BAYER CORP. COMBINATION ASPIRIN	:	<b>JURY TRIAL DEMAND</b>
PRODUCTS MARKETING AND SALES	:	
PRACTICES LITIGATION	:	09 MD 2023 (BMC)
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	:	THIS DOCUMENT RELATES
	:	TO MCCABE, et al. v.
	:	BAYER HEALTHCARE LLC,
	:	et al.
	:	
	:	Case No. 1:09-cv-01541-BMC
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Plaintiffs, ANNE MCCABE and FRANCES MARTINEZ, on behalf of themselves and all California consumers similarly situated, and demanding trial by jury, complain and allege upon information and belief as follows:

### **INTRODUCTION**

1. This action was originally filed in the California Superior Court for the County of San Diego (SCSD Case No. 37-2008-00096471) on November 19, 2008. On December 31, 2008, Defendant BAYER HEALTHCARE L.L.C. (“BAYER”) filed a Notice of Removal to the Southern District of California (SD CAL Case No. 08-cv-2417-JAH (BLM)). On April 15, 2009, this case was transferred to the Eastern District of New York pursuant to order of the Judicial Panel on Multidistrict Litigation (“JMDL”). Prior to transfer by the JMDL, on January 22, 2009 plaintiffs filed a motion for remand, which was not decided. Plaintiffs do not concede or allege, directly or indirectly, federal jurisdiction and expressly reserve all rights to challenge such jurisdiction.

2. On November 19, 2008, pursuant to California Civil Code, section 1782, Plaintiffs ANNE MCCABE and FRANCES MARTINEZ, on behalf of a class of all California consumers who purchased BAYER DRUG DIETARY SUPPLEMENT PRODUCTS, sent to BAYER a letter, return receipt requested, demanding that it cease its practices of marketing BAYER DRUG DIETARY SUPPLEMENT PRODUCTS as treatments for heart and bone diseases and to refund the purchase prices paid by Plaintiffs and all other California consumers for these products. Over thirty days has elapsed since that letter was received by BAYER and it has not agreed to cease marketing these products as treatments for heart and bone diseases. Nor has it agreed to refund plaintiffs’ and California consumers’ purchase prices for these products. Pursuant to California Civil Code, section 1782, Plaintiffs file this amended complaint to add claims for compensatory and punitive damages under their Consumer Legal Remedies Act cause of action.

3. This civil consumer protection class action is brought to remedy violations of California's Sherman Food, Drug, and Cosmetic Law, Health & Safety Code §109875, et seq., Consumers Legal Remedies Act, Civil Code §1750 et seq. ("CLRA") Unfair Competition Law, Business & Professions Code §17200 et seq. ("UCL"), False Advertising Law Business & Professions Code §17500 et seq. ("FAL"), and Negligent Misrepresentation, Civil Code §§1709-1711, statutes and in connection with defendants' course of conduct, including misrepresentations and omissions, in the manufacture, sale and marketing of "BAYER ASPIRIN WITH HEART ADVANTAGE" ("Bayer Heart Advantage") and "BAYER WOMEN'S LOW DOSE ASPIRIN + CALCIUM" ("Bayer Women's"), which are marketed as drug dietary supplement products. (Bayer Heart Advantage and Bayer Women's are collectively referred to hereafter as "BAYER DRUG DIETARY SUPPLEMENT PRODUCTS" or "BAYER DRUGS"). BAYER markets BAYER DRUG DIETARY SUPPLEMENT PRODUCTS as effective treatments for prevention of heart and bone disease. BAYER was required to obtain FDA approval prior to marketing these products as treatments for these diseases and is specifically prohibited by the Cal. Health & Safety Code from advertising or representing that such drugs have any effect on bone and joint or heart and vascular diseases. These statutes and regulatory approval processes exist to protect the public. However, BAYER has failed to obtain the regulatory approval required to market the BAYER DRUGS as over-the-counter ("OTC") drugs and markets them on the basis of claims that these drugs have effects on bone and joint or heart and vascular diseases. BAYER's marketing and sale of the BAYER DRUGS has thus short-circuited the proper regulatory process and put consumer health and welfare at risk. At the same time, BAYER's practices undermine the efforts of honest competitors who comply with regulatory procedures.

4. The BAYER DRUGS are "misbranded". BAYER has made misleading representations and has failed to adequately disclose significant safety risks associated with the use of its products that combine aspirin with phytosterols (Bayer Heart Advantage) and aspirin with calcium (Bayer's Women's). In addition to marketing the BAYER DRUGS as OTC pain relievers, BAYER markets and advertises them as capable of reducing the risks of certain diseases including osteoporosis and heart disease. Federal and state law requires drugs that treat bone and heart

disease to receive regulatory approval prior to marketing and generally bans such drugs from OTC sales all together. According to the United States Food and Drug Administration (“FDA”), because the BAYER DRUG DIETARY SUPPLEMENT PRODUCTS are new formulations, they cannot be legally marketed in the U.S. until they receive approval. The FDA has found that neither drug is approved for uses other than pain treatment (like ordinary aspirin). BAYER has been marketing the drugs in the U.S. as OTC products. BAYER’s marketing of these drugs as treatment for osteoporosis and heart disease, without prior FDA approval to treat those conditions, is a *per se* violation of the California Health & Safety Code.

5. BAYER reaps significant profits from its misbranding and unlawful marketing, advertising, and labeling of Bayer Heart Advantage and Bayer Women’s because it sells these products at prices several times the price of ordinary of low dosage aspirin. Due to BAYER’s unlawful marketing, consumers pay more for these products, believing that these products have received regulatory approval to treat bone and heart disease when they in fact, have not.

### **JURISDICTION AND VENUE**

6. Plaintiffs allege jurisdiction pursuant to California Health & Safety Code §111910, Civil Code §1780, Business and Professions Code §§ 17203, 17204, 17500, and other provisions of California law. This complaint is not based on federal law. The amount in controversy for each named class representative is less than \$75,000.00.

7. Plaintiffs allege venue as to each defendant was proper pursuant to California Code of Civil Procedure §§ 395 and 395.5, California Civil Code § 1780, and California Business & Professions Code §§ 17202 and 17203 and other provisions of California law. Defendants, transact business, have an agent, or are found in the County of San Diego and are within the jurisdiction of this Court. The unlawful acts alleged herein had a direct effect on consumers within the State of California and, more particularly, within the County of San Diego.

### **DEFINITIONS**

8. References made herein to any business entity include any predecessors, successors, parents, subsidiaries, affiliates, and divisions of that entity.

9. As used herein, “dietary supplement(s)” means products (other than tobacco) that are intended to supplement the diet and which contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by humans to supplement the diet by increasing the total intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.

10. As used herein, “BAYER DRUG DIETARY SUPPLEMENT PRODUCTS” means Bayer Heart Advantage, Bayer Women’s or any product containing aspirin and calcium or aspirin and phytosterols that is manufactured, marketed, sold, advertised or otherwise placed into the stream of commerce, directly or indirectly, by the defendants named herein and each of them.

11. As used herein, “phytosterols,” also known as plant sterols, are a group of steroid alcohols, phytochemicals naturally occurring in plants.

12. As used herein, “person(s)” has the same meaning as set forth in Business and Professions Code §17201, Civil Code §1761, and Health & Safety Code §109995.

13. As used herein, “consumer(s)” has the same meaning as set forth in Civil Code §1761.

14. As used herein, “advertisement” has the same meanings as set forth in Health & Safety Code §109885 and as applied to the UCL and FAL.

15. As used herein, “drug” has the same meaning as set forth in Health & Safety Code §109925.

16. As used herein, “label” and “labeling” have the same meanings as set forth in Health & Safety Code §§109955 and 109960, respectively.

17. As used herein, “new drug” has the same meanings as set forth in 21 U.S.C. § 321(p)) and 21 C.F.R. § 310.3(h) and Health & Safety Code §109980.

18. As used herein, “misbranding” has the same meanings as set forth in Health & Safety Code §§111330-111510, and generally means labeling that “is false or misleading in any particular.”

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**THE PARTIES**

**A. Plaintiffs**

19. Representative Plaintiff Anne McCabe is a resident of the State of California, who, during the relevant Class Period, purchased Bayer Women's for her own use and not for resale. The damages or losses as to plaintiff individually do not exceed \$75,000.00, however calculated, and no federal questions are asserted herein.

20. Representative Plaintiff Frances Martinez is a resident of the State of California, who, during the relevant Class Period, purchased Bayer Heart Advantage for her own use and not for resale. The damages or losses as to plaintiff individually do not exceed \$75,000.00, however calculated, and no federal questions are asserted herein.

**B. Defendants**

21. Defendant BAYER HEALTHCARE L.L.C. develops, manufactures, markets and sells vitamins, minerals, herbal, nutritional supplements, pharmaceutical products and consumer "health" products, including BAYER DRUG DIETARY SUPPLEMENT PRODUCTS. BAYER is a limited liability company qualified to do business in and transacting substantial business in the State of California. BAYER HEALTHCARE L.L.C (including its corporate affiliates) has numerous facilities in California ranging from manufacturing and warehouse facilities, to advanced research and development laboratories, including business units that are headquartered here. BAYER has more facilities in California than in any other state. California is BAYER's place of operation for BAYER DRUG DIETARY SUPPLEMENT PRODUCTS based upon the amount of trade and commerce in BAYER DRUG DIETARY SUPPLEMENT PRODUCTS and the predominance of BAYER's facilities in California. The acts complained of, which are the subject matter of this class action, occurred, in substantial part, in the State of California and in this county. During the period of time covered by this complaint, BAYER engaged in the business of, among other things, designing, manufacturing, marketing, selling, advertising, distributing, promoting or otherwise placing into the stream of commerce in California, directly or indirectly, BAYER DRUG DIETARY SUPPLEMENT PRODUCTS.

22. The true names and capacities, whether individual, corporate, associate, representative, or otherwise of defendants named herein as DOES 1-50 are unknown to plaintiffs at this time, and are therefore sued by such fictitious names pursuant to Code of Civil Procedure §474. Plaintiffs will amend this complaint to allege the true names and capacities of DOES 1-50 is in some manner legally responsible for the violations of the law alleged herein.

### **CLASS ACTION ALLEGATIONS**

23. Pursuant to California Code of Civil Procedure §382 and Civil Code §1781, plaintiffs bring this action individually and as a class action on behalf of themselves and all California consumers similarly situated.<sup>1</sup> The class that plaintiffs seek to represent (the “Plaintiff Class”) is composed of, and identified, as follows:

All consumers, residing in the state of California, who purchased in California for their own use and not for resale, BAYER DRUG DIETARY SUPPLEMENT PRODUCTS (as defined herein) within the three years prior to the filing of this complaint through the date of class notice. Specifically excluded from the Plaintiff Class are the defendants herein, officers, directors and employees of defendants, and any entity in which defendants have a controlling interest; the agents, affiliates, legal representative, heirs, attorneys at law, attorneys in fact or assignees of the defendants; and any federal, state or local government entity. Also specifically excluded, are any justice, judge, judicial officer, court personnel or juror assigned to any part of this case.

24. This action has been brought and may be properly maintained as a class action, pursuant to the provisions of §382 of the California Code of Civil Procedure and Civil Code §1781 because there is a well-defined community of interest in the litigation and the proposed class is easily ascertainable.

A. Numerosity: The Plaintiff Class is so numerous that individual joinder of all members is impractical under the circumstances of this case. While the exact number of class members is unknown to plaintiffs at this time, based upon the amount of trade and commerce in the dietary supplement and pharmaceutical product industry plaintiffs are

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<sup>1</sup> Further including Federal Rules of Civil Procedure, Rule 23, if applicable.  
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informed and believe that BAYER sells many millions of dollars worth of BAYER DRUG DIETARY SUPPLEMENT PRODUCTS in California annually. Plaintiffs are informed and believe that the Plaintiff Class includes many thousands of members located throughout California.

B. Common Questions of Law and Fact: Common questions of law and fact exist as to all members of the Plaintiff Class and predominate over any questions which affect only individual members of the Plaintiff Class. These common questions of law and fact include, without limitation:

1. Whether defendants' conduct violated the California Health & Safety Code;
2. Whether defendants' conduct violated the CLRA;
3. Whether defendants' business acts or practices violated the UCL;
4. Whether defendants' conduct violated the FAL;
5. Whether defendants engaged in negligent misrepresentation in violation of Civil Code §§1709-1711;
6. The class-wide nature of defendants' course of conduct;
7. The amount of additional revenues and profits obtained by defendants attributable to their unlawful conduct;
8. The appropriate nature of class-wide equitable relief including corrective and remedial action;
9. Whether the members of the Plaintiff Class are entitled to restitution as a result of defendants' conduct and, if so, what is the proper measure and appropriate formula to be applied in determining such restitution;
10. Whether the members of the Plaintiff Class have sustained damages as a result of defendants' conduct and, if so, what is



the proper measure and appropriate formula to be applied in determining such damages; and

11. Whether the members of the Plaintiff Class are entitled to punitive and exemplary damages as a result of defendants' acts of fraud, malice and oppression or in conscious disregard of the rights of plaintiffs and the Plaintiff Class, and, if so, what is the proper amount of such punitive and exemplary damages.

C. Typicality: Plaintiffs' claims are typical of the claims of the members of the Plaintiff Class. Plaintiffs and all members of the Plaintiff Class sustained injuries and damages arising out of defendants' common course of conduct in violation of the laws complained of herein. The injuries of each Class Member were caused directly by BAYER's wrongful conduct in violation of the law as alleged herein.

D. Adequacy: Plaintiffs will fairly and adequately protect the interests of the members of the Plaintiff Class. Plaintiffs purchased BAYER DRUG DIETARY SUPPLEMENT PRODUCTS during the Class Period, and are adequate representatives of the Class as they have no interests which are adverse to the interests of absent Class Members. Plaintiffs have retained counsel who have substantial experience and success in the prosecution of complex consumer protection class actions of this nature.

25. The policies, procedures and practices described herein relating to the BAYER DRUG DIETARY SUPPLEMENT PRODUCTS are part of a common course of conduct of unlawful deceptive acts and practices undertaken by defendants. As a result, the issues affecting plaintiffs and all members of the Plaintiff Class in common, predominate over those which affect only the interests of any individual Class Member.

26. A class action is superior to other available means for the fair and efficient adjudication of this controversy since individual joinder of all members of the Plaintiff Class is impractical. Furthermore, as the damages or injuries suffered by each individual member of the Class may be relatively small, the expenses and burden of individual litigation would make it difficult or impossible for individual members of the Class to redress the wrongs done to them.

The cost to the court system of adjudications of individualized litigation would be substantial. Individualized litigation would also present the potential for inconsistent or contradictory judgments.

## **FACTUAL ALLEGATIONS**

### **BACKGROUND**

27. High levels of cholesterol, and particularly low density lipoproteins (“LDL”), have been linked to heart and vascular disease in humans. Numerous prescription medications are legitimately marketed to reduce cholesterol and the associated risks of heart and vascular disease.

28. Phytosterols are plant-derived compounds that are similar in structure and function to cholesterol. High intakes of plant sterols can lower LDL cholesterol concentrations in humans.<sup>2</sup>

29. Phytosterols combined with aspirin (e.g. Bayer Heart Advantage) is a drug and is subject to the FDA’s OTC Drug Review. Because no product formulated with these active ingredients and labeled for these intended uses has previously been commercially marketed, the FDA has never included that product in its OTC Drug Review. Accordingly, the combination of phytosterols and aspirin has never been approved by the FDA as a treatment for heart disease.

30. Calcium is a mineral found mainly in the hard part of bones, where it is stored. Calcium is added to bones by cells called osteoblasts and is removed from bones by cells called osteoclasts. Calcium is essential for healthy bones. It is also important for muscle contraction, heart action, nervous system maintenance, and normal blood clotting.

31. Osteoporosis is a disorder characterized by porous, fragile bones. It is a serious public health problem for more than 10 million Americans, 80% of whom are women. Another 34 million Americans have osteopenia, or low bone mass, which precedes osteoporosis. Osteoporosis is a concern because of its association with fractures of the hip, vertebrae, wrist, pelvis, ribs, and other bones. In recognition of the serious public health implications of

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<sup>2</sup> Berger A, Jones PJ, Abumweis SS. Plant sterols: factors affecting their efficacy and safety as functional food ingredients. *Lipids Health Dis.* 2004;3(1):5. ([PubMed](#))  
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osteoporosis, the California Legislature has enacted the "California Osteoporosis Prevention and Education Act", Health & Safety Code §125700, *et seq.*

32. In 1993 the FDA authorized a health claim on calcium and osteoporosis for food labels in response to scientific evidence that an inadequate calcium intake is one factor that can lead to low peak bone mass and is considered a risk factor for osteoporosis. However, calcium in combination with aspirin (e.g. Bayer Women's) is classified as a drug and is subject to the FDA's OTC Drug Review. Because no product formulated with these active ingredients and labeled for these intended uses has previously been commercially marketed, the FDA has never included that product in its OTC Drug Review. Accordingly, the combination of calcium and aspirin has never been approved by the FDA as a treatment for osteoporosis.

**BAYER HAS NEVER SOUGHT REGULATORY APPROVAL FOR ITS COMBINATION  
ASPIRIN AND CALCIUM/PHYTOSTEROL DRUGS**

33. Dietary supplements are not required to undergo pre-market clearance by the FDA. Under the Dietary Supplement Health and Education Act of 1994, herbal supplements are exempt from the FDA's rigorous pharmaceutical regulation. They therefore do not need to undergo any scientific proof of safety. Manufacturers need not register or get FDA approval before producing or selling dietary supplements. In most instances, sellers of dietary supplements are prohibited from making health or other claims of efficacy. However, BAYER is labeling Bayer Heart Advantage and Bayer Women's as a combination of a drug and dietary supplement in a single tablet and claims that they are effective to treat bone and heart disease. As such, BAYER DRUG DIETARY SUPPLEMENT PRODUCTS are drugs within the meaning of 21 U.S.C. § 321(g)(1)(B)) and(C) and Health & Safety code §109925. The FDA requires drugs of this nature to be approved before marketing and bans such drugs from OTC sales altogether. The FDA has found that BAYER has not received approval from the FDA to make claims that the BAYER DRUG DIETARY SUPPLEMENT PRODUCTS treat osteoporosis or heart disease. Accordingly,

BAYER's marketing and labeling of these drugs as treatments for osteoporosis and heart disease violates California Health & Safety Code § 110403.

**RISKS ASSOCIATED WITH BAYER DRUG DIETARY SUPPLEMENT PRODUCTS**

34. BAYER markets, advertises and labels BAYER DRUG DIETARY SUPPLEMENT PRODUCTS as OTC medications, but their use requires a physician's supervision. Products that are being marketed for preventing heart attacks, for preventing and/or treating heart disease, and/or treating osteoporosis require the supervision of a physician to ensure safe use.

35. BAYER represents that Bayer Heart Advantage product has been "proven to help reduce the risk of a heart attack by up to 32% in appropriate patients." BAYER also claims that phytosterols help lower LDL (bad) cholesterol and "Aspirin helps prevent blood clots and can cut the risk of a heart attack by up to 32%" and "By lowering cholesterol, phytosterols can help prevent plaque buildup."

36. Regarding the use of Bayer Heart Advantage as a source of aspirin, the Drug Facts panel on the package labeling states that the analgesic is intended to treat pain. However, other statements and representations on the package indicate that Bayer Heart Advantage is also intended for long-term daily use in preventing heart attacks and lowering cholesterol, and therefore in preventing and treating cardiovascular disease and hypercholesterolemia. Moreover, the labeled directions for adult analgesic use specify a daily dosage of "4 caplets, not to exceed 4 caplets in 24 hours," which falls within the range of the dosages listed in the professional labeling for aspirin for cardiovascular-related indications (see 21 C.F.R. § 343.80), but is well below the dosages that are listed in the tentative final monograph for internal analgesics for adults and children 12 and over (325 to 650 milligrams every four hours or 325 to 500 milligrams every three hours or 650 to 1,000 milligrams every six hours, not to exceed 4000 milligrams in twenty-four hours, or as directed by a doctor). See 53 FR 46204 at 46257.

37. As labeled, Bayer Heart Advantage is a “drug” under § 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(g)(1)(B)) and California Health & Safety Code §109925, because it is intended to be used as an internal analgesic and to mitigate, treat, or prevent disease (specifically, heart disease and hypercholesterolemia), and under § 201(g)(1)(C) of the Act (21 U.S.C. § 321 (g)(1)(C)) because it is intended to affect the structure or the function of the body.

38. Bayer Women’s packaging provides a health claim on the package labeling that calcium “helps strengthen bones to fight osteoporosis.” The claim is not a health claim under 21 C.F.R. § 101.72, but rather a claim to treat, mitigate, or prevent osteoporosis under § 201(g)(1)(B) of the Act (21 U.S.C. § 321 (g)(1)(B)) and California Health & Safety Code §110403 .

39. Based on the combination of the active drug ingredients (i.e., aspirin and calcium carbonate) and their combined labeled uses in mitigating, treating, or preventing cardiovascular-related diseases and osteoporosis, Bayer Women’s is a new drug within the meaning of § 201(p) of the Act (21 U.S.C. § 321(p)) and 21 C.F.R. § 310.3(h) and Health & Safety Code §109980, because it is not generally recognized as safe and effective for its labeled uses.

40. The BAYER DRUGS have not been proven safe and effective for their labeled uses.

### **BAYER’S MISLEADING AND DECEPTIVE PRACTICES**

41. BAYER has attempted to market Bayer Health Advantage as a combination drug-dietary supplement. However, the presence of aspirin in this product, with its intended uses as an analgesic to mitigate, treat and prevent heart disease, render the entire product a drug. The phytosterols in this product could be marketed separately as a dietary supplement if the health and efficacy claims, “Plus Cholesterol Lowering Phytosterols” and “Phytosterols, to help lower bad cholesterol,” were removed and no other cholesterol-lowering claims were made, except as provided for in 21 C.F.R. § 101.83 as part of an explanation of the mechanism by which

phytosterols reduce the risk of heart disease. When, as here, a drug and a dietary ingredient are combined into a single dosage form, the combination becomes a “drug” under section 210(g) of the Act (21 U.S.C. § 321(g)). BAYER has misled and deceived consumers to believe that this product is not a drug, but rather a supplement, and has been proven to be safe and effective.

42. There is no provision in the Act, as amended by the Nutrition Labeling and Education Act of 1990 (NLEA) or by the Dietary Supplement Health and Education Act of 1994 (DSHEA) that exempts any part of Bayer Heart Advantage product from the scope of section 201(g) of the Act (21 U.S.C. § 321(g)). Under section 201(g)(1)(D) of the Act (21 U.S.C. § 321(g)(1)(D)), and California’s Health & Safety Code, the phytosterols used in combination with the aspirin in Bayer Heart Advantage are also drugs, even in the absence of any claims that phytosterols treat, mitigate, or prevent hypercholesterolemia or heart disease, because the phytosterols are components of the finished drug product.

43. In addition, Bayer Heart Advantage is misbranded under section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)) and California’s Health & Safety Code because it does not bear adequate directions for its intended uses, i.e., for preventing heart attacks and preventing/treating heart disease in general. “Adequate directions for use” is defined in 21 C.F.R. § 201.5 as “directions under which the layman can use a drug safely for the purposes for which it is intended.” Thus, if an indication requires the supervision of a practitioner licensed to prescribe drugs, adequate directions for use cannot be written for an OTC product for that indication. *See U.S. v. Articles of Drug*, 625 F. 2d 665, 672-673 (5th Cir. 1980). As described in 21 C.F.R. § 343.80, cardiovascular indications accordingly are permissible only in the professional labeling for aspirin. Under that regulation, manufacturers are not permitted to disseminate labeling for their OTC aspirin products to lay consumers for cardiovascular-related indications.

44. Bayer Heart Advantage is also misbranded under sections 502(f)(2) and 502(a) of the Act (21 U.S.C. §§ 352(f)(2) and California’s Health & Safety Code because labeling does not bear adequate warnings and is misleading. Warnings that appear within the “Drug Facts” panel are both inconsistent and incompatible with the directions elsewhere on the labeling that recommend the daily consumption of Bayer Heart Advantage as a source of dietary

phytosterols. Furthermore, the placement of warnings within the perimeter of the “Drug Facts” panel, and the separate “Supplement Facts” panel and directions for use that do not include those warnings, suggests that the information in the “Drug Facts” panel pertains only to the uses of the product listed in that panel, and that such warnings are not relevant when using the product for the phytosterols component. (See Attachment A). Thus, the labeled warnings are not adequate, and are misleading because they are undermined by the inconsistent and incompatible language pertaining specifically to the phytosterols component. Persons using this product to supplement their diet may overlook or disregard the importance of these warnings, or may be unsure as to their relevance when there are no such warnings associated with the supplemental portion of the labeling, and as a result, adverse events may occur.

45. In addition, Bayer Women’s is misbranded under section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)) and California’s Health & Safety Code because it does not bear adequate directions for its intended uses, i.e., for treating osteoporosis, for preventing heart attacks, and for preventing/treating heart disease in general. “Adequate directions for use” is defined in 21 C.F.R § 201.5 as “directions under which the layman can use a drug safely for the purposes for which it is intended.” Thus, if an indication requires the supervision of a practitioner licensed to prescribe drugs, adequate directions for use cannot be written for an OTC product for that indication. *See U.S. v. Articles of Drug*, 625 F. 2d 665, 672-673 (5th Cir. 1980). As described in 21 C.F.R. § 343.80, cardiovascular indications accordingly are permissible only in the professional labeling for aspirin. Under that regulation, manufacturers are not permitted to disseminate labeling for their OTC aspirin products to lay consumers for cardiovascular-related indications.

46. Bayer Women’s is also misbranded under sections 502(f)(2) and 502(a) of the Act (21 U.S.C. §§ 352(f)(2) and California’s Health & Safety Code because labeling does not bear adequate warnings and is misleading. Warnings that appear within the “Drug Facts” panel are both inconsistent and incompatible with the directions elsewhere on the labeling that recommend the daily consumption of Bayer Women’s as a source of dietary calcium. Furthermore, the placement of warnings within the perimeter of the “Drug Facts” panel, and the

separate “Supplement Facts” panel and directions for use that do not include those warnings, suggests that the information in the “Drug Facts” panel pertains only to the uses of the product listed in that panel, and that such warnings are not relevant when using the product for the calcium component. (See Attachment B). Thus, the labeled warnings are not adequate, and are misleading because they are undermined by the inconsistent and incompatible language pertaining specifically to the calcium component. Persons using this product to supplement their diet may overlook or disregard the importance of these warnings, or may be unsure as to their relevance when there are no such warnings associated with the supplemental portion of the labeling, and as a result, adverse events may occur.

47. By virtue of the unlawful labeling, marketing, and advertising alleged herein, BAYER was able to charge significantly more for BAYER DRUGS than if it was aspirin. For example, retail prices of Bayer’s Heart Advantage are at least six to ten times as high per pill, as for an equivalent amount of normal BAYER aspirin, which far exceed any incremental cost related to the inclusion of calcium or phytosterols. BAYER was able to charge and collect this overcharge in the sale of BAYER DRUGS because plaintiffs and the Plaintiff Class reasonably believed that these drugs were safe and effective treatments for osteoporosis and heart disease as indicated by BAYER and that these products had been approved for these uses by federal law or regulatory authorities or pursuant to state law. In reality, the BAYER DRUGS have never been tested or approved for the uses advertised by BAYER.

**FIRST CAUSE OF ACTION**  
**Violations of the Sherman Food, Drug, and Cosmetic Act**  
**California Health & Safety Code § 109875 *et seq.***  
**(All Plaintiffs Against All Defendants)**

48. Plaintiffs, on behalf of themselves and all California consumers similarly situated, reallege, as if fully set forth herein, each and every allegation contained in Paragraphs 1 through 47 hereof.

49. Defendants have marketed and advertised Bayer Heart Advantage as a treatment and prevention for heart disease.



50. Defendants have marketed and advertised Bayer Women's as a treatment and prevention for bone disease, including osteoporosis.

51. Defendants have not received approval from the FDA to market these products to treat heart disease or bone disease.

52. California Health & Safety Code § 110403 makes it unlawful for any company to advertise that any drug has any effect on bone or heart disease unless that drug has been approved for that use by the FDA. Accordingly, defendants' marketing of these drugs as treatments for heart and bone disease is a *per se* violation of California law.

53. Defendants have disseminated false and misleading advertisements and marketing materials concerning, mislabeled, and misbranded BAYER DRUG DIETARY SUPPLEMENT PRODUCTS in violation of the California Health & Safety Code.

54. Defendants have offered and sold BAYER DRUG DIETARY SUPPLEMENT PRODUCTS by means of false advertisements in violation of the California Health & Safety Code.

55. Defendants' marketing of the BAYER DRUG DIETARY SUPPLEMENT PRODUCTS as drugs for the treatment of osteoporosis and heart disease constitutes misbranding under California's Health & Safety Code.

56. Defendants' acts as described herein have violated other provisions of the California Health & Safety Code.

57. Plaintiffs, and the members of the Plaintiff Class, accordingly are entitled to equitable relief including injunctive relief, remedial or corrective action, full restitution and/or disgorgement, as well as attorney's fees.

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**SECOND CAUSE OF ACTION**  
**Violations of the Consumers Legal Remedies Act**  
**California Civil Code § 1750 *et seq.***  
**(All Consumers Against All Defendants)**

58. Plaintiffs, on behalf of themselves and all California consumers similarly situated, reallege, as if fully set forth herein, each and every allegation contained in Paragraphs 1 through 57 hereof.

59. The acts and practices as alleged herein constituted and constitute unlawful methods of competition, unfair, or deceptive acts undertaken in a transaction which resulted in the sale of goods to consumers including, but in no way limited to, representing that goods and services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that defendant has a sponsorship, approval, status, affiliation, or connection which it does not have.

60. Plaintiffs seek an order enjoining the above-described wrongful acts and practices of defendants and awarding restitution, recession or disgorgement of defendants' revenues and profits from the sale of BAYER DRUG DIETARY SUPPLEMENT PRODUCTS.

61. Approximately one in two women and one in four men over age 50 will have an osteoporosis related fracture in their remaining lifetime.<sup>3</sup> The Surgeon General warns that persons over the age of 65 face a significant increased risk of osteoporosis.<sup>4</sup> Nearly 75% of hip, spine and distal forearm fractures occur among patients 65 years old or over.<sup>5</sup> Bayer markets Bayer Women's to *inter alia*, persons who are 65 years or older, because they are more likely to suffer from bone diseases and disorders such as osteoporosis. Defendants knew and understood that their conduct alleged herein would affect persons over the age of 65.

62. Men over the age of 45 and women over the age of 55 who have elevated levels of LDLs face an increased risk of heart attack and heart disease.<sup>6</sup> BAYER markets Bayer

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<sup>3</sup> National Osteoporosis Foundation, <http://www.nof.org/osteoporosis/diseasefacts.htm#prevalence>

<sup>4</sup> See 2004 Surgeon General's Report on Bone Health and Osteoporosis  
<http://www.surgeongeneral.gov/library/bonehealth/docs/OsteoBrochure1mar05.pdf>

<sup>5</sup> Melton LJ, 3rd, Crowson CS and O'Fallon WM (1999) Fracture incidence in Olmsted County, Minnesota: comparison of urban with rural rates and changes in urban rates over time. *Osteoporos Int* 9:29.

<sup>6</sup> National Institute of Health: High Blood Cholesterol: What You Need to Know  
<http://www.nhlbi.nih.gov/health/public/heart/chol/wyntk.htm#risk>

Heart Advantage to *inter alia*, persons who are 65 years or older, because they are more likely to suffer from high LDL levels and heart disease. Defendants knew and understood that their conduct as alleged herein would effect persons over the age of 65.

63. As a direct and proximate result of defendants' violations of the CLRA as alleged herein, plaintiffs and members of the Class have been injured including, *inter alia*, by:

A. the infringement of their legal rights as a result of being subjected to the common course of conduct alleged herein;

B. plaintiffs and the members of the Class were induced to purchase aspirin containing calcium or phytosterols from defendants, which they would not have done had they been fully informed of defendants' acts, omissions, misrepresentations, practices and nondisclosures as alleged in this complaint, in violation of, *inter alia*, the CLRA;

C. plaintiffs and the members of the Class were induced to rely on defendants' deceptive representations to their detriment as a result of defendants' conduct as alleged in this complaint, in violation of, *inter alia*, the CLRA;

D. plaintiffs and members of the Class have unknowingly been subjected to significant risks without their knowledge or consent.

64. Defendants' acts, statements, representations, policies and procedures as described herein were knowingly deceptive and were made with conscious disregard of the effects upon consumers. Defendants are required by law to make adequate disclosure of the true safety of its goods to potential consumers. Defendants failed to do so in order to conceal their acts, omissions, misrepresentations, practices and nondisclosures as alleged in this complaint, and to induce customers to purchase the aspirin containing calcium and/or phytosterols from defendants. Accordingly, defendants engaged in acts of fraud, malice and oppression or in conscious disregard of the rights or safety of the plaintiffs and the members of the Plaintiff Class.

65. On or about November 19, 2008 plaintiffs sent BAYER a notice pursuant to Civil Code section 1782(a). BAYER failed to act as required in Civil Code section 1782(c)

within the time required. Accordingly, plaintiffs seek and are entitled to compensatory and punitive damages in an amount to be proved at trial.

66. In addition to restitution and other equitable relief as provided by the CLRA, as a direct and proximate result of the violations of the CLRA as alleged herein, plaintiffs and the Plaintiff Class have suffered damages in an amount to be proved at the time of trial.

67. Further, the violations of the CLRA as alleged herein were committed by means of fraud, malice and oppression, including conscious disregard of legal rights, thereby entitling plaintiffs and the Plaintiff Class to punitive and exemplary damages in an amount to be proved at the time of trial.

68. Plaintiffs have filed a declaration pursuant to Civil Code section 1780(c).

**THIRD CAUSE OF ACTION**  
**For Violation of the Unfair Competition Law,**  
**California Business and Professions Code §§ 17200 *et seq.***  
**(All Plaintiffs Against All Defendants)**

69. Plaintiffs, on behalf of themselves and all California consumers similarly situated, reallege, as if fully set forth herein, each and every allegation contained in Paragraphs 1 through 68 hereof.

70. All marketing, advertising, publicity and promotional efforts as described herein undertaken by defendants concerning the safety of goods and services in connection with the BAYER DRUG DIETARY SUPPLEMENT PRODUCTS, constitutes unfair competition, in violation of California Business and Professions Code § 17200 *et seq.*, the Unfair Competition Law (“UCL”). Defendants have and continue to engage in conduct that is unlawful, unfair or fraudulent through a pattern of misrepresentation and concealment of material facts that misleads and deceives the public with respect to the true nature and safety of the BAYER DRUG DIETARY SUPPLEMENT PRODUCTS, by marketing, offering and selling them as non-drug supplements and a pattern of failing to warn consumers about the safety of the product through false and misleading statements and deceptive and unfair policies, procedures and acts.

71. The acts, omissions, misrepresentations, practices and nondisclosures of defendants, as alleged herein, constituted and continue to constitute unfair, unlawful and/or fraudulent business practices within the meaning of Business and Professions Code § 17200 *et seq.*, including, but in no way limited to, the following:

A. the violation of the Business and Professions Code § 17500 *et seq.*, (“FAL”);

B. the violation of Civil Code § 1750 *et seq.*, the Consumer Legal Remedies Act (“CLRA”), set forth in this complaint;

C. violation of Section 5 of the Federal Trade Commission Act (15 U.S.C. § 45(a));

D. violation of Sherman Food, Drug, and Cosmetic Laws, Health and Safety Code § 109875 *et seq.*, the related acts and regulations;

E. violation of the federal FDA act, the related acts and regulations;

F. Defendants’ acts, omissions, misrepresentations, practices, and nondisclosures as set forth in this complaint, whether or not in violation of the laws set forth herein, are otherwise unfair, unconscionable, unlawful and fraudulent;

i. Defendants’ acts and practices are unfair to consumers in the State of California within the meaning of Business and Professions Code § 17200 *et seq.*, and

ii. Defendants’ acts and practices are fraudulent within the meaning of the Business and Professions Code § 17200 *et seq.*

72. Plaintiffs, and the members of the Plaintiff Class, accordingly are entitled to equitable relief including injunctive relief, remedial or corrective action, full restitution and/or disgorgement of defendants’ revenues and profits from the sale of BAYER DRUG DIETARY SUPPLEMENT PRODUCTS.

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**FOURTH CAUSE OF ACTION**  
**Violation of False Advertising Law,**  
**California Business and Professions Code §§ 17500 *et seq.***  
**(All Plaintiffs Against All Defendants)**

73. Plaintiffs, on behalf of themselves and all persons similarly situated, reallege, as if fully set forth herein, each and every allegation contained in Paragraphs 1 through 72 hereof.

74. The advertising, marketing and other promotional efforts undertaken by defendants constitute advertising devices disseminated by defendants from and into California, which contained and continue to contain statements and omissions of material facts concerning the legality, safety, efficacy, and nature of BAYER DRUG DIETARY SUPPLEMENT PRODUCTS that are untrue and/or misleading in violation of California Business and Professions Code §§ 17500 *et seq.*, the False Advertising Law (“FAL”).

75. Plaintiffs, and the members of the Plaintiff Class, accordingly are entitled to equitable relief including injunctive relief, remedial or corrective action, full restitution and/or disgorgement of defendants’ revenues and profits from the sale of BAYER DRUG DIETARY SUPPLEMENT PRODUCTS.

**FIFTH CAUSE OF ACTION**  
**Negligent Misrepresentation**  
**California Civil Code §§ 1709, 1710 & 1711**  
**(All Plaintiffs Against All Defendants)**

76. Plaintiffs, on behalf of themselves and all California consumers similarly situated, reallege, as if fully set forth herein, each and every allegation contained in Paragraphs 1 through 75 hereof.

77. Defendants have made express and implied representations to plaintiffs and the members of the Plaintiff Class and omitted to state material facts in connection with the sale marketing and advertising of the BAYER DRUGS.

78. Defendants made the aforesaid representations without reasonable grounds for believing them to be true, and omitted facts which were necessary, under the circumstances, to make their representations and related practices concerning BAYER DRUGS not misleading.

79. Defendants' misrepresentations and omissions were uniform and part of a common course of conduct directed to plaintiffs and the members of the Plaintiff Class.

80. Plaintiffs and the Plaintiff Class were induced to purchase BAYER DRUGS based on defendants' misrepresentations and omissions of material fact.

81. Defendants intended and expected plaintiffs and the Plaintiff Class to rely on the false and untrue representations and omissions to induce plaintiffs and the Plaintiff Class to purchase BAYER DRUGS. Had plaintiffs and the Plaintiff Class known the true facts, they would not have taken such action.

82. As a direct and proximate result of defendants' negligent misrepresentations and omissions, plaintiffs and the Plaintiff Class have suffered damages in an amount to be proved at the time of trial. In the alternative, plaintiffs and the Plaintiff Class are entitled to all sums by which defendants have been unjustly enriched.

#### **PRAYER FOR RELIEF**

WHEREFORE, the Representative Plaintiffs, on behalf of themselves and all persons and consumers similarly situated and residing in California, pray for judgment against defendants as follows:

1. that an order certifying the Class defined herein be entered designating plaintiffs and their counsel as representatives of said Class;
2. that defendants be ordered to make restitution to each plaintiff and each member of the Plaintiff Class under each cause of action in an amount according to proof at trial;
3. for injunctive relief against defendants under each cause of action;
4. for a statutory award of up to \$5,000 for each class member sixty-five years of age and older for violations of the CLRA;
5. for compensatory damages in an amount according to proof under their CLRA and Negligent Misrepresentation Causes of Action;
6. for punitive and exemplary damages in amounts according to proof at trial in accordance with the CLRA;

7. for other equitable relief;
8. for attorney's fees as provided by law;
9. for prejudgment interest as provided by law;
10. for costs of suit; and
11. for such other and further relief as this Court deems to be just and equitable.

Respectfully Submitted,

Dated: May 7, 2009

By: /s/ Daniel J. Mogin

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*Attorneys for Plaintiffs and the Proposed Plaintiff Class*



**JURY TRIAL DEMAND**

Plaintiffs hereby demand a trial by jury.

Dated: May 7, 2009

By: /s/ Daniel J. Mogin

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*Attorneys for Plaintiffs and the  
Proposed Plaintiff Class*

# **Attachment A**

N 0280-2230-12  
ANALGESIC/PHYTOSTEROL SUPPLEMENT

**BAYER**<sup>®</sup>  
ASPIRIN

**With HEART ADVANTAGE**

**LOW DOSE**  
**ASPIRIN PLUS**  
**81<sup>mg</sup>**  
**CHOLESTEROL LOWERING**  
**PHYTOSTEROLS**

**More for Heart Protection:**

- Aspirin, to protect your heart by keeping your blood flowing freely
- Phytosterols, to help lower bad cholesterol\*

See Back Panel\*

Aspirin is not appropriate for everyone, so be sure to talk to your doctor before you begin or change an aspirin regimen.

**120**  
DUO-CAPS



**Drug Facts**

**Active ingredient (in each caplet)** Aspirin 81 mg

**Purpose** Pain reliever

**Uses**

- for the temporary relief of minor aches and pains or as recommended by your doctor.
- ask your doctor about other uses for Bayer® Aspirin with Heart Advantage

**Warnings**

**Reye's syndrome:** Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include:

- hives
- asthma (wheezing)
- facial swelling
- shock

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.

**Drug Facts (continued)**

**Do not use** if you are allergic to aspirin or any other pain reliever/fever reducer

**Ask a doctor before use if you have**

- stomach problems (such as heartburn, upset stomach, or stomach pain) that last or come back
- bleeding problems
- ulcers
- asthma

**Ask a doctor or pharmacist before use if you are taking a prescription drug for**

- anticoagulation (blood thinning)
- gout
- diabetes
- arthritis

**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or loss of hearing occurs

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Drug Facts (continued)**

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- talk to your doctor about regimen use of aspirin
- drink a full glass of water with each dose
- for pain, adults and children 12 years and over: take 4 caplets, not to exceed 4 caplets in 24 hours
- children under 12 years: consult a doctor

**Other information**

- each caplet contains: phytosterols 400 mg
- save card for full directions and warnings
- store at room temperature

**Inactive ingredients** anhydrous citric acid, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C yellow #5 (tartrazine) aluminum lake, hypromellose, lactose, microcrystalline cellulose, powdered cellulose, pregelatinized starch, triacetin, zinc stearate

**Questions or comments?** 1-800-331-4536 (Mon - Fri 9AM - 5PM EST) or [www.bayeraspirin.com](http://www.bayeraspirin.com)

**Directions:** For phytosterols, adults and children 12 years and over, take one caplet twice daily with meals or as directed by your doctor.

**Supplement Facts**

Serving Size: One Caplet

	Amount Per Serving	% Daily Value
Phytosterols	400 mg	*

\*Daily Value not established.  
Not a significant source of iron.

**Ingredients:** Phytosterols, Aspirin, Microcrystalline Cellulose, Lactose, Croscarmellose Sodium, Corn Starch, Powdered Cellulose, Pregelatinized Starch, Hypromellose, FD&C Yellow #5 (tartrazine) Aluminium Lake, Colloidal Silicon Dioxide, Triacetin, Carnauba Wax, Zinc Stearate, Anhydrous Citric Acid.

**Contains:** Milk.

For additional product information, see Drug Facts.

\*DIETARY SUPPLEMENTS OR FOOD CONTAINING AT LEAST 400MG PER SERVING OF FREE PHYTOSTEROLS, EATEN TWICE A DAY WITH MEALS FOR A DAILY TOTAL INTAKE OF AT LEAST 800MG, AS PART OF A DIET LOW IN SATURATED FAT AND CHOLESTEROL, MAY REDUCE THE RISK OF HEART DISEASE BY LOWERING BLOOD CHOLESTEROL.  
EACH BAYER ASPIRIN WITH HEART ADVANTAGE DUO-CAP CONTAINS 400MG OF FREE PHYTOSTEROLS.

THIS PRODUCT IS NOT A REPLACEMENT FOR CHOLESTEROL-LOWERING MEDICATIONS.

**Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.**



**Bayer HealthCare**

Bayer HealthCare LLC  
Consumer Care  
P.O. Box 1910  
Morristown, NJ 07962-1910 USA

Bayer and the Bayer Cross are trademarks of Bayer.



C0698

# **Attachment B**



**Si**  
Sen  
Dire year

**COATED CAPLETS**